REMARKS

The present Office Action addresses and rejects claims 1-18.

At the outset, Applicants would like to thank Supervisory Examiner Hindenburg and Examiner Rogers for extending the courtesy of a telephone interview with Applicants' attorney on September 14, 2006. During the interview, the pending rejections and prior art were discussed. Applicants proposed general claim amendments for overcoming the art of record. Although no formal agreement was reached, the Examiners were willing to enter and consider the amendments, and acknowledged that the claims, as amended, might be found to distinguish over the prior art.

Independent claim 1 has been amended to recite that the outer cannula of the bone marrow sampling device includes a sidewall with an outer surface that forms an exterior surface of the device. Claim 1 has also been amended to recite that the plurality of openings in the sidewall of the outer cannula of the device are formed at least at a distal portion of the outer cannula. Support for these amendments can be found throughout the specification, for example, at page 4, lines 13-22; page 6, lines 1-4; page 10, lines 6-17; and FIG. 3. No new matter has been added.

Claim Objections

Claim 1 is objected to as containing informalities. The Examiner suggests the phrase "...defining a inner lumen..." should be corrected to recite "...defining an inner lumen..." Applicants have amended claim 1 to comport with the suggested correction.

Claim Rejections – 35 U.S.C. § 102

Bryan et al.

Claims 1, 5-6, 11-14, and 17 are rejected pursuant to 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,488,636 to Bryan *et al.* ("Bryan").

As discussed with the Examiners during the telephone interview, Applicants are amending claim 1 to include a limitation which clarifies the structural features of the claimed invention, which Applicants believe renders claim 1 distinguishable over the Bryan reference.

In particular, independent claim 1 has been amended to clarify that the outer cannula recited in claim 1 is the outer-most cannula of the bone marrow sampling device. Thus, claim 1 now further recites that the sidewall of the outer cannula includes an outer surface that forms an exterior surface of the bone marrow sampling device. While Bryan discloses a biopsy device that includes a cutting tube (24) which forms the outer-most cannula of the insertion portion (12) of the device, Bryan lacks any teaching or suggestion that the cutting tube (24) include a plurality of openings formed in a sidewall thereof. *See Bryan et al.*, FIGS. 2 and 12. Rather, Bryan discloses only a *single* opening (102) in cutting tube (24). *See* FIGS. 11, 13 and 23. Conversely, claim 1 requires that the outer cannula have a sidewall with a *plurality* of openings; the plurality of openings being spaced apart at different radial and longitudinal positions on the sidewall. Moreover, the singular opening (102) of the Bryan device is located at a *proximal* position on the cutting tube (24). In contrast, amended claim 1 now recites that the plurality of openings in the sidewall are located at a *distal* portion of the outer cannula. In addition, Bryan fails to disclose the outer cannula (24) itself having a closed distal end and a tissue penetrating tip, as further required by claim 1. Rather, as shown in FIG. 2 of Bryan, cutting tube (24) has an open distal end through which extends tip (13) of the inner thrust tube (16). Therefore, the biopsy apparatus of Bryan fails to disclose the structural features of the claimed invention.

Accordingly, Bryan does not teach or even suggest the limitations of amended claim 1, and Applicants respectfully request withdrawal of the rejection of independent claim 1 in view of Bryan. In addition, Applicants believe claims 5-6, 11-14, and 17, are allowable at least because they depend from an allowable base claim.

Burbank et al.

Claims 1-7, 8-11 and 16-17 are rejected pursuant to 35 U.S.C. § 102(b) as anticipated by U.S. Pub. No. 2002/0193705 to Burbank *et al.* ("Burbank").

As indicated to the Examiner during the telephone interview, Applicants are amending claim 1 to include a structural limitation which Applicants believe renders claim 1 distinguishable over the teachings of Burbank.

Specifically, amended independent claim 1 now recites that the outer cannula includes a plurality of openings formed *at least at a distal portion* of the outer cannula. Burbank lacks any teaching or even suggestion of an outer cannula having a plurality of openings formed at a distal portion thereof. Instead, the plurality of openings (218) to which the Examiner refers to in the device of Burbank, are, in fact, located at a *proximal* position of the outer cannula (152). The Examiner points to FIG. 7 of Burbank in support of the contention that the plurality of openings (218) are at a distal position. However, the "Brief Description of Drawings" section of Burbank explicitly states that "FIG. 7 is a schematic illustration of *proximal* portions of a cannula." Emphasis added; *Burbank et al.*, pg. 3, ¶ 32. Moreover, the specification of Burbank clearly discloses that the plurality of openings (218) are formed at proximal portion of outer cannula (152). Specifically, Burbank describes an outer cannula (152) having a singular cut-out window (162) formed at a *distal* portion thereof; the outer cannula (152) preferably including a "mesh, screen, or array (216)" with a plurality of openings (218), the screen (216) being "provided along outer cannula (152) *proximal* of cutout (162)." Emphasis added; *See* FIG. 4a; pg. 4, ¶ 55 – pg. 5, ¶ 56. Burbank in no way teaches or suggests that the plurality of openings (218) can be provided at a distal portion of outer cannula (152), such as, for example, in place of the cut-out (162), as required by the claimed invention. Applicants also believe that the proximal placement of the openings (218) is essential for the intended function of the Burbank device (vapor aspiration) and placement of these openings at any other location would compromise this intended function.

Burbank teaches that the sole function of the plurality of openings (218) of outer cannula (152) is to aspirate any vapors resulting during the use of the RF energy cutting elements of the cannula assembly (102). *See Burbank et al.*, pg. 6, ¶¶ 68-69. Conversely, claim 1 recites that the plurality of openings of the outer cannula serve to collect tissue samples, by, e.g., drawing bone marrow into the inner lumen of the inner cannula. Burbank lacks any suggestion that the plurality of openings (218) are capable of drawing a tissue sample into the inner lumen of inner cannula (116), as required by the claimed invention. Rather, the Burbank reference explicitly describes the cut-outs (162, 124) of the outer cannula (152) and inner cannula (116), respectively, as the window for drawing a tissue sample into the inner lumen (122) of the inner cannula (116). *See* pg. 7, ¶¶ 77-78. Therefore, Burbank fails to disclose the claimed invention.

Accordingly, Burbank does not teach or even suggest the limitations of amended claim 1, and Applicants respectfully request withdrawal of the rejection of independent claim 1 in view of Burbank. In addition, Applicants believe claims 7, 8-11 and 16-17 are allowable at least because they depend from an allowable base claim.

Claim Rejections – 35 U.S.C. § 103

Dependent claims 2-4, 7-10, 15-16, and 18 are rejected pursuant to 35 U.S.C. § 103(a) as obvious over Bryan in view of the references: U.S. Pub. No. 2003/0050574 of Krueger ("Krueger"); U.S. Pub. No. 2003/0093008 of Van Bladel *et al.* ("Van Bladel"); U.S. Pat. No. 5,810,826 of Akerfeldt *et al.* ("Akerfeldt"); and U.S. Pub. No. 2002/0016555 of Ritchart *et al.* ("Ritchart"). Dependent claims 12-15 and 18 are rejected pursuant to 35 U.S.C. § 103(a) as obvious over Burbank in view of the references: U.S. Pat. No. 6,733,479 of Ott ("Ott") and Krueger.

Applicants' arguments raised above with respect to Bryan and Burbank and independent claim 1, apply with equal force to dependent claims 2-18 which all depend from claim 1. As discussed previously, Bryan and Burbank both fail to teach the salient features of the amended claimed invention. Further, neither Bryan or Burbank appreciate the applicability and use of a bone marrow sampling device that enables samples to be withdrawn from different areas within a patient's bone marrow without having to reposition the sampling device, thereby reducing the pain and discomfort suffered by a patient during bone marrow collection. Neither are the deficiencies of Bryan and Burbank remedied by the teachings of any of the secondary references.

Krueger

Krueger is cited to teach the size and configuration of the withdrawal apertures set forth in claim 2-3, 7; and the indicia described in claim 18. However, the wording of these claims specifically refers to, and relies upon, the limitation that the outer cannula has a sidewall with a plurality of openings. Conversely, Krueger is entirely absent of any teaching of an outer cannula having a plurality of openings. Instead, Krueger describes a trough (13) and openings (16) formed in an sampling cannula (10) that is positioned *within* an outer cannula (20). *See Krueger*, pg. 2, ¶ 30; pg. 3, ¶¶ 43-44; FIG. 4. The reference lacks any suggestion or even hint that the outer cannula (20) can include a plurality of openings in a sidewall thereof, as required by the claimed invention.

Therefore, Krueger cannot teach aligning the openings of an inner cannula with openings of an outer cannula to create a withdrawal aperture of a particular configuration, as recited in claims 2 and 3. Neither can Krueger disclose openings in the sidewall of an outer cannula having a minimum distance, as recited in claim 7. Nor does Krueger teach indicia which indicate when an opening of the inner cannula lines up with an opening of the outer cannula, as recited in claim 18. In addition, Krueger fails to teach an outer cannula having a closed distal end and a penetrating tip as further required by the claimed invention. Therefore, Krueger fails to remedy any of the deficiencies of Bryan and Burbank, and thus, cannot render obvious the claimed invention, taken either alone or in combination.

Van Bladel et al.

Van Bladel is cited to teach the dimensions of the outer cannula as set forth in claim 4. However, the biopsy device described by Van Bladel fails to disclose or suggest several of the salient structural features of independent claim 1. In particular, Van Bladel does not disclose an outer cannula with a sidewall having an outer surface that forms an exterior surface of a device, and a plurality of openings in the sidewall thereof, the outer cannula further having a closed distal end and tissue penetrating tip, as required by the claimed invention. Van Bladel simply teaches a biopsy device including a cannula (5) with a straight-cut open distal edge (6), and a biopsy needle (20) fitted within the lumen of the cannula (5). *See Van Bladel et al.*, pg. 2, ¶¶ 16-17; FIG. 2. The reference lacks any suggestion that cannula (5) include either a plurality of openings, or a closed distal end or a tissue penetrating tip, as required by the outer cannula of the claimed invention. Accordingly, Van Bladel fails to remedy any of the deficiencies of Bryan, and does not render obvious claim 4.

Akerfeldt et al.

Akerfeldt is cited to teach an inner and outer cannula with translational and rotational movement, as set forth in claims 8-10. Akerfeldt is generally directed to a device for puncturing cortical bone and includes an outer cannula (2) having an open distal end and an inner needle (5). The needle can include an eccentrically shaped tip. However, nowhere does Akerfeldt teach or suggest an outer cannula including the structural limitations as recited in independent claim 1,

limitations that are likewise lacking in Bryan. Therefore, Akerfeldt also fails to remedy the deficiencies of Bryan. Accordingly, Akerfeldt, taken either alone or in combination, cannot render obvious dependent claims 8-10.

Ritchart et al.

Ritchart is cited to teach a second inner cannula having a channel in a sidewall for delivery of treatment material, and automated movement of the inner and outer cannula, as set forth in claims 15-16. Ritchart is directed to a soft tissue biopsy device having a hollow outer piercing needle (20) and an inner cutter (22) having a lumen. However, Ritchart fails to disclose several of the structural features required by the device as recited in independent claim 1, from which claim 15-16 depend. In particular, Ritchart does not teach needle (20) having a sidewall with a plurality of openings formed at a distal end thereof and spaced apart at different radial and longitudinal positions on the sidewall, a limitation similarly lacking in the device of Bryan, yet required by claim 1. Further, Ritchart lacks any suggestion of providing inner cutter (22) with at least one opening formed in a sidewall thereof, as recited by the claimed invention. In addition, Richart does not disclose selective relative movement between an inner and outer cannula which enables a device to be configured in multiple bone marrow sampling modes such that openings in the sidewall of the inner cannula can be aligned with different openings in the sidewall of the outer cannula, as taught the present invention. As such, even if Ritchart and Bryan could be combined, a person skilled in the art would not arrive at a bone marrow sampling device including all the limitations as recited by independent claim 1. Accordingly, Ritchart, taken either alone or in combination, fails to render obvious dependent claims 15-16.

Ott

Ott is cited to teach a second inner cannula as set forth in claims 12-15. However, the deficiencies of Burbank are not overcome by combining it with Ott. In particular, Ott fails to teach an outer cannula having a closed distal end and a tissue penetrating tip, an inner cannula with a least one opening. Instead, Ott simply teaches an trocar sleeve (21) with an open distal end (26) and a lumen (28) for passing a plurality of medical instruments (14) therethrough. *See Ott*, Col. 5, lns 46-54. While Ott discloses an inner sheath (62) for use within the outer trocar sleeve (21), Ott does not

teach at least one opening formed in the inner sheath (62). Further, the Ott reference is entirely absent of a *second* inner cannula disposed between the inner and outer cannula, which provides such functional limitations as required by claims 12-15. Therefore, Ott, taken either alone or in combination, fails to render obvious claims 12-15.

Accordingly, none of the secondary references, either alone or in combination with Bryan or Burbank, teach the limitations of the claimed invention, and Applicants respectfully request withdrawal of the rejection of dependent claims 2-18. In addition, Applicants believe claims 2-18 are allowable at least because they depend from an allowable base claim.

CONCLUSION

In summary, it is believed that the amended claims are in condition for allowance, and reconsideration is respectfully requested for all the reasons set forth above. The Examiner is urged to telephone the undersigned Attorney for Applicants in the event that such communication is deemed to expedite prosecution of this matter.

Dated: September 18, 2006

Respectfully submitted,

By _____

William C. Geary III
Registration No.: 31,359
NUTTER MCCLENNEN & FISH LLP
World Trade Center West
155 Seaport Boulevard
Boston, Massachusetts 02210-2604
(617) 439-2766
(617) 310-9766 (Fax)
Attorney for Applicant

1560455.1